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(54) Title: FAT WITH SPECIFIC ANTISCLEROSIS EFFECTS			
(57) Abstract			
<p>Fat with specific antisclerosis effects, especially to consumed fat, margarine, halvarine or vegetable butter, containing partly at least 25 percent basic fat phase, which consists of oil and/or hardened vegetable oil and possibly an additional animal fat, partly the additive, which decreases cholesterol level and/or reduces the development of cholesterol in the blood. Said additive which decreases the level and/or reduces the development of cholesterol in the blood is formed by hypolipidemics from a group of essential phospholipids and/or vitamin PP, alternative by its derivatives and/or by statins.</p>			

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Fat with specific antisclerosis effects.Field of the invention.

This invention relates to fat with specific antisclerosis effects, especially to consumed fat, margarine, halvarine or vegetable butter, containing on partly at least 25 percent basic fat phase, which consists of oil and/or hardened vegetable oil and possibly an additional animal fat, and partly containing the additives which decreases cholesterol level and/or reduces the development of cholesterol in the blood.

Description of the prior art.

One of the basic factors affecting the incidence of diseases involving atherosclerosis is hyperlipoproteinemia. It has been recently found that up to 90 percent of population is showing signs of cholesterol increase in the blood, especially LDL cholesterol.

One of the recent ways of reducing total cholesterol levels and especially LDL cholesterol is to change dietary habits to lower the amount of fat consumption and to select consumend fat such as margarine, halvarine and vegetable butter with considerably lower fat content and at the same time with a higher content of essential amino acids. Recently, there has been a production of fats and margarine where one of the components is part of a group of plant sterols such as sitosterol, campesterol or brassicasterol. A disadvantage of these is that they are derived from pine wood (WO 92/19640) in environmentally unfriendly way.

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If the reduction of the cholesterol level through the said change of dietary habits is unsuccessful or insufficient, and if the consumption of parts of the group plant sterols is unsuccessful too then, one must firmly reduce overall cholesterol level as well as LDL cholesterol in the blood by adopting chemotherapeutic treatment using hypolipidemics that then directly affects the area of synthesis of cholesterol or LDL cholesterol during metabolic processes. The said chemotherapeutics are applied according to the medical prescription combined or not with other supporting substances such as vitamins e.g. vitamin A, vitamin B,E. The shortcoming of the said application of hypolipidemics is, that they are used after the high level of cholesterol has already caused health problems. In addition it is necessary to these substances in relatively high doses and under doctor's supervision.

Disclosure of the invention.

The purpose of the invention is to prevent hypercholesterolemia by spreading the above said hypolipidemics widely among the population so as to avoid their consequential medical prescription.

This purpose solved the subject-matter of the invention, which is a fat with specific antisclerosis effects, especially to consumed fat, margarine, halvarine or vegetable butter, containing partly at least 25 percent basic fat phase, which consists of oil and/or hardened vegetable oil and possibly an additional animal fat, partly the additive which decreases cholesterol level and/or reduces the development of cholesterol in the blood.

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The nature of this invention is, that the additive which decreases cholesterol level and/or reduces the development of cholesterol in the blood is created by hypolipemics from a group of essential phospholipides and/or vitamin PP, alternative by its derivatives and/or by statins.

Another nature of the invention is, that fat mixture of 1.000 units of weight contains 250 to 995 units of weight of fat phase, up to 4,5 units of weight of hypolipemics and up to 12,5 units of weight of additives, with the remainder being completed of water.

The further nature of the invention is, that fat mixture of 1.000 units of weight contains 250 to 995 units of weight of fat phase, 0,5 to 20 units weight of essential phospholipides, up to 5 units of weight of other vitamins, up to 40 units of weight of emulgators and up to 5,9 units of weight of other additives, with the remainder being completed of water,

or that fat mixture of 1.000 units of weight contains 250 to 995 units of weight of fat phase, 0,5 to 20 units of weight of vitamin PP or its derivatives, up to 5 units of weight of other vitamins, up to 40 units of weight of emulgators, up to 40 units of weight of gelatine and/or modified starches and/or pectines, up to 17 units of weight of other additives, with the remainder being completed of water,

or finally that fat mixture of 1.000 units of weight contains 250 to 995 units of weight of fat phase, 0,1 to 5 units of weight of statins, up to 5 units of weight of other vitamins, up to 5 units of weight of flavourings, up to 40 units of weight of emulgators, up to 50 units of weight of gelatine and/or modified starches and/or pectines, up to 10 units of weight of salt and up to 2 units of weight of sorbic acid and/or its alkaline salts, with the remainder being completed of water.

The advantage of the applied substances from a group of hypolipidemics according to the invention is, that its defined substances form organic part in the consumed fats, margarines, halvarines or vegetable butters and are through the mediation of them applied in a small and at the same time unarmful or supportive quantitatives consumed in common fats and foods in the course of the day, that contain such fats.

Another considerable advantage of the fats consisted according to the invention is, that they mostly forms water/fat or fat/water emulsion, which are not commonly used for high temperature preparing of other foods and therefore they are not exposed to such temperature changes, that could deteriorate additives.

So it is possible to apply such a preparation in this way among the general population in natural way, especially as margarine and halvarine, which on the one hand reduces intake of lipids to the human organism, on the other ensures preventive influence of the effective substances, based on statins, vitamin PP in different forms, or essential phospholipids.

Examples of the fat-mixtures according to the invention.

The basic fat component according to the invention mentioned in the following examples is formed by liquid and/or hardened vegetable oil such as rapessed oil, sunflower oil, soybean oil, palm oil or palmolein, or its combinations and alternately with other vegetable oils, that are made of products of vegetable origin by analogic technical processing by pressing and/or extracting. It is possible to add a little animal fat, formed mainly of milk fat, liquid or hardened fat or tallow, to said

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mixture. Optionally, those components, or sam of them, could be replaced by analogic animal fats without effects to the invention.

The basic fat phase applied in the following examples is illustrated in the following types:

Type A:

Mixture of 0,7 to 0,8 units of weight of sunflower oil and 0,2 to 0,3 units of weight of hardened rapessed oil.

Type B:

Mixture of 0,1 to 0,14 units of weight of rapessed oil, 0,6 to 0,7 unit of weight of hardened rapessed oil, 0,07 to 0,09 units of weight of liquid lard and 0.1 to 0,2 units of weight of hardened lard.

Type C:

Mixture of 0,26 to 0,30 units of weight of rapessed oil; 0,40 to 0,50 units of weight of hardened rapessed oil, 0,1 to 0,14 units of weight of hardened palm oil, 0,03 to 0,07 units of weight of liquid lard, 0,03 to 0,07 units of weight of liquid lard, 0,03 to 0,07 units of weight of hardened lard and 0,03 to 0,07 units of weight of tallow.

Type D:

Mixture of 0,75 to 0,85 units of weight of liquid soybean oil and 0,15 to 0,25 units of weight of hardened rapessed oil.

The examplatory types of structure of fat phases are indicated by letters A to D,

that correspond with the mixture mentioned above to simplify the following examples. The basic fat phase be enriched by the fat and/or by water soluble form of particular hypolipidemics according to the invention, or its combination.

If needed be the mixture is completed by other supporting media such as vitamins or flavourings, so that in the end there are fat acquired with specific antisclerotic effects with the following exploratory structure.

Example 1: Fat of which 1000 g contains
998,475 g of fat phase type A
1,5 g of essential phospholipides
0,005 g of vitamin PP
0,01 g of pyridoxin hydrochloride
0,005 g adenosin triphosphate
0,005 g of vitamin E

Example 2: Fat of which 1000 g contains
250 g of fat phase type B
1 g of essential phospholipides
0,05 g of vitamin PP
0,001 g of statins
40 g of gelatine
2 g of salt
20 g of kalium sorbate
20 g of emulgators
0,01 g of pyridoxin hydrochlorid

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0,005 g of adenosin triphosphate
0,005 g vitamin E
684,929 g of water

Example 3:

Fat of which 1000 g contains

400 g of fat phase type C
1 g of essential phospholipides
0,1 g of vitamin PP
0,001 g of statins
10 g of emulgators
15 g of salt
0,5 g of kalium sorbate
0,5 g of vitamin E
0,1 g of vitamin A
572,79 g of water

Example 4:

Fat of which 1000 g contains

990 g fat of phase type C
10 g of essential phospholipides

Example 5:

Fat of which 1000 g contains

250 g of fat phase type C
15 g of essential phospholipides
40 g of gelatine
2 g of salt
2 g of kalium sorbate

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20 g of emulgators
671 g of water

Example 6:

Fat of which 1000 g contains
400 g of fat phase type B
10 g of essential phospholipides
10 g of emulgators
10 g of salt
0,5 g of kalium sorbate
0,5 g of vitamin E
0,1 g of vitamin A
568,9 g of water

Example 7:

Fat of which 1000 g contains
995 g of fat phase type D
5 g of vitamin PP and/or its derivatives

Example 8:

Fat of which 1000 g contains
250 g of fat phase type B
10 g of vitamin PP and/or its derivatives
40 g of gelatine
2 g of salt
2 g of kalium sorbate
20 g of emulgators
676 g of water

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Example 9:

Fat of which 1000 g contains

400 g of fat phase type C

1 g of vitamin PP and/or its derivatives

10 g of emulgators

3 g of salt

0,5 g of kalium sorbate

0,5 g of vitamin E

0,1 g of vitamin A

584,9 g of water

Example 10:

Fat of which 1000 g contains

999,5 g of fat phase type A

0,5 g of statins

Example 11:

Fat of which 1000 g contains

250 g of fat phase type B

0,15 g of statins

40 g of gelatine

2 g of salt

2 g of kalium sorbate

20 g of emulgators

685,85 g of water

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<u>Example 12:</u>	Fat of which 1000 g contains
400	g of fat phase type C
0,1	g of statins
10	g of emulgators
18	g of salt
0.5	g of kalium sorbate
0,5	g of vitamin E
0,1	g of vitamin A
570,8	g of water

In the examples of said fat phase, its applications in the connection with others components, especially with particular types of hypolipidemics according to the invention, as well as applications of others, e.g. components of vitamins and/or flavourings, are not the only variations possible for realization of the invention. It is evident that it is possible to realize other combinations of the said substances without effecting disclosure of the invention, if the amount of the final fat in the unit is kept within the limits defined in the claims.

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C l a i m s .

1. Fat with specific antisclerosis effects, especially to consumed fat, margarine, halvarine or vegetable butter, containing partly at least 25 percent basic fat phase, which consists of oil and/or hardened vegetable oil and possibly an additional animal fat, partly the additive which decreases cholesterol level and/or reduces the development of cholesterol in the blood, characterized by that the additive which decreases cholesterol level and/or reduces the development of cholesterol in the blood is created by hypolipidemics from a group of essential phospholipides and/or vitamin PP, alternatively by its derivatives and/or by statins.
2. Fat according to the claim 1, characterized by that its 1.000 units of weight contains
 - 250 to 995 units of weight of fat phase,
 - up to 4,5 units of weight of hypolipidemics,
 - up to 12,5 units of weight of additives,which components are completed up to 1.000 units of weight with water.
3. Fat according to the claim 1, fat phase of which consists of vegetable fat, alternative with addition of animal fat, characterized by that its 1.000 units of weight contains
 - 250 to 995 units of weight of fat phase,
 - 0,5 to 20 units of weight of essential phospholipides,
 - up to 5 units of weight of other vitamins,
 - up to 40 units of weight of emulgators,
 - up to 5,9 units of weight of other additives,which components are completed up to 1.000 units of weight with water.

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4. Fat according to the claim 1, fat phase of which consist of vegetable fat, alternative with addition of animal fat, characterized by that its 1.000 units of weight contains

250 to 995 units of weight of fat phase,
0,5 to 20 units of weight of vitamin PP or its derivatives,
up to 5 units of weight of other vitamins,
up to 40 units of weight of emulgators,
up to 40 units of weight of gelatine and/or modified
starches and/or pectines,
up to 17 units of weight of other additives,
which components are completed up to 1.000 units of weight with water.

5. Fat according to the claim 1, fat phase of which consist of vegetable fat, alternative with addition of animal fat, characterized by that its 1.000 units of weight contains

250 to 995 units of weight of fat phase,
0,1 to 5 units of weight of statins,
up to 5 units of weight of other vitamins,
up to 5 units of weight of flavourings,
up to 40 units of weight of emulgators,
up to 50 units units of weight of gelatine and/or modified
starches and/or pectines,
up to 10 units of weight of salt,
up to 2 units of weight of sorbic acid and/or its alkaline salts
which components are completed up to 1.000 units of weight with water.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A2309/007 A23D7/00 A61K31/455 A61K31/23 A61K31/66
A61K31/685

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A23D A61K A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 148 303 A (VON MLETZKO ARMIN DR) 17 July 1985 see page 1, line 21 - page 6, line 27 see claims 1-9 ---	1
Y	DE 26 07 654 A (HOFFMANN LA ROCHE) 16 September 1976 see example 1 --- -/--	1

☒ Further documents are listed in the continuation of box C.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	H. GYLLING ET AL.: "Effects of inhibiting cholesterol absorption and synthesis on cholesterol and lipoprotein metabolism in hypercholesterolemic non-insulin-dependent diabetic men" JOURNAL OF LIPID RESEARCH, vol. 37, no. 8, 1996, pages 1776-1785, XP002056770 see page 1776, column 1, Abstract see page 1777, column 1, paragraph 2 - column 2, paragraph 3 see page 1778, column 2, paragraph 7 - page 1783, column 2, last paragraph ---	1
A	L. ROZEWICKA ET AL.: "Effect of essential phospholipids on the lipid content in the liver and myocardium of rats fed a high-fat diet" FOLIA BIOLOGICA, vol. 26, no. 4, 1978, KRAKOW, POLAND, pages 249-255, XP002056771 see the whole document ---	1
A	FR 2 133 508 A (INST BIOCHIMIE) 1 December 1972 see claim 9 ---	1
A	DATABASE WPI Section Ch, Week 8350 Derwent Publications Ltd., London, GB; Class A96, AN 83-842468 XP002056772 & RO 81 579 A (INST CERC CHIMICO-FARM), 30 April 1983 see abstract ---	1
A	FR 2 466 459 A (FABRE SA PIERRE) 10 April 1981 see page 2, line 24 - line 29 see claim 10 ---	1
A	FR 2 704 556 A (RHONE POULENC RORER SA :ROUSSY INST GUSTAVE: CENTRE NAT RECH SCIEN) 4 November 1994 see page 2, line 8 - line 16 ---	1
P,A	WO 96 34855 A (SCOTIA HOLDINGS PLC :HORROBIN DAVID F (GB): MANKU MEHAR (GB); MCMO) 7 November 1996 see page 27, line 4 - line 5 see page 38, line 12 - line 13 -----	1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CZ 97/00038

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0148303 A	17-07-85	NONE	
DE 2607654 A	16-09-76	NONE	
FR 2133508 A	01-12-72	NONE	
FR 2466459 A	10-04-81	NONE	
FR 2704556 A	04-11-94	AU 6572294 A	21-11-94
		BR 9406689 A	30-01-96
		CA 2161679 A	10-11-94
		EP 0701450 A	20-03-96
		FI 955154 A	27-10-95
		WO 9425073 A	10-11-94
		JP 8509373 T	08-10-96
		NO 954286 A	26-10-95
		ZA 9402980 A	18-01-95
WO 9634855 A	07-11-96	AU 5507996 A	21-11-96
		AU 5508096 A	21-11-96
		AU 5508196 A	21-11-96
		EP 0823895 A	18-02-98
		EP 0823889 A	18-02-98
		EP 0823897 A	18-02-98
		WO 9634846 A	07-11-96
		WO 9634858 A	07-11-96
		NO 975035 A	22-12-97
		NO 975036 A	17-12-97

